K002357 P1 of 3

NOV - 9 2000

510(k) Summary
100S/100LC/485 Anser
Pie Medical

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 5779070

Contact Person: Colleen Hittle

Date: July 21, 2000

807.92(a)(2)

Trade Name:	100S/100LC/485 Anser Ultrasound Imaging Systems	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
Classification Number:	90IYO	

807.92(a)(3)

Predicate Device(s)

Pie Medical	480	K911584
	250	K915647

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
100S/100LC/485 Anser
Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's 100S/100LC/485 Anser ultrasound systems used are to perform general diagnostic ultrasound studies.

K002357 P3 of 3

510(k) Summary
100S/100LC/485 Anser
Pie Medical

Comparison Chart for Substantial Equivalence

	Pie MERA Endorectal Probe (K911043)	**PIE 400/450 (Predicate to 1150, cleared via K874192)**	**PIE 1150 (Predicate to 250, cleared via K900469)**	**PIE 250 (Predicate to 240, cleared via K915647**	**PIE 100S To be cleared with this submission**	**PIE 100LC To be cleared with this submission**	**PIE 480 (Predicate to 485 Anser, cleared via 510(k) 911584**	**PIE 485 Anser To be cleared with this submission**
Technology	Annular	Linear	Linear Curved Mechanical Annular	Annular Curved Linear	Annular	Linear Curved	Linear	Curved/Linear
Modes	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+B, B+M, M	B, B+B, B+M, M
Frequencies	5.0 – 7.5 MHz	3.5 – 7.5 MHz	3.5 – 7.5 MHz	3.5-7.5 MHz	3.5-7.5 MHz	3.5-8MHz	3.5 – 7.5 MHz	3.5 – 8 MHz
Applications	Urological Transrectal	Abdominal Fetal Pediatric Small Organs Intraoperative Neonatal Cephalic	Abdominal Fetal Pediatric Small Organs Intraoperative	Abdominal Small Organ Intraoperative Pediatric Peripheral Vascular Fetal	Abdominal Transvaginal Cardiac Fetal Small Organs Transrectal Pediatric Peripheral Vascular Intraoperative Musculoskeletal	Abdominal Transvaginal Fetal Pediatric Small Organs Transrectal Intraoperative Peripheral Vascular Cardiac Musculosketal	Abdominal Small Organ Pediatric Fetal	Abdominal Small Organ Transvaginal Transrectal Intraoperative Neonatal Cephalic Pediatric Peripheral Vascular Fetal Musculosketal

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2000

Pie Medical
c/o Colleen Hittle
Official Correspondent
The Anson Group
800 Castleway Drive
Indianapolis, IN 46250

Re: K002357
100S,100LC, and 485 Anser Ultrasound Imaging Systems
Regulatory Class: II
21CFR892.1560/Procode: 90 IYO
21CFR892.1570/Procode: 90 ITX
Dated: October 30, 2000
Received: October 31, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ultrasound systems listed below, as described in your premarket notification:

Transducer Model Numbers for the 100S Ultrasound Imaging System

402144
402154
402155
402156

Transducer Model Numbers for the 100LC Ultrasound Imaging System

401612
401664
401665
401667
401669
401671
401788
410054

Transducer Model Numbers for the 485 Anser Ultrasound Imaging System

401612
401664
401665
401667
401669
401788
410054

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

100S System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

✓

David A. Seymour

Prescription Use ~~(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)~~
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Applicable Combined Modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100S - #402154

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K002357

100S - #402156

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal		E	E						E	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

David A. Segrom

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David A. Stigen

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC - 401612

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined modes = B+B; B+M

David A. Hyman

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC - #401664

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

David A. Seymour

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC - #401665

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David G. Hyman

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC - #401669

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

David A. Flynn

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use √
(Per 21 CFR 801.109)

510(k) Number K002357

100LC - #401671

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal										
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David G. Hyman

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC - #401788 Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal		N	N						N	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David A. Flynn

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

100LC - #410054

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		E	E						E	
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David A. Lyon

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

485 Anser System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		E	E						E	
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David A. Bysm

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

485 Anser - 401612

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined modes = B+B; B+M

David A. Lyon

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

David B. Hoffman

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(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

485 Anser - #401667

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		E	E						E	
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

Prescription Use ✓
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Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K002357

485 Anser - #401669

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002357

485 Anser - #401788

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David A. Seguin

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002357

485 Anser System # 410054

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

David A. Lyerson

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